

The PRESIDING OFFICER. Without objection, it is so ordered.

#### SUBCOMMITTEE ON CRIME AND TERRORISM

Mrs. BOXER. Mr. President, I ask unanimous consent that the Committee on the Judiciary, Subcommittee on Crime and Terrorism, be authorized to meet during the session of the Senate, on May 8, 2013, at 9 a.m., in room SD-226 of the Dirksen Senate Office Building, to conduct a hearing entitled "Cyber Threats: Law Enforcement and Private Sector Responses."

The PRESIDING OFFICER. Without objection, it is so ordered.

#### SUBCOMMITTEE ON EMERGENCY MANAGEMENT, INTERGOVERNMENTAL RELATIONS, AND THE DISTRICT OF COLUMBIA

Mrs. BOXER. Mr. President, I ask unanimous consent that the Subcommittee on Emergency Management, Intergovernmental Relations, and the District of Columbia of the Committee on Homeland Security and Governmental Affairs be authorized to meet during the session of the Senate on May 8, 2013, at 2:30 p.m. to conduct a hearing entitled, "The Role of the Private Sector in Preparedness and Emergency Response."

The PRESIDING OFFICER. Without objection, it is so ordered.

#### SUBCOMMITTEE ON SEAPOWER

Mrs. BOXER. Mr. President, I ask unanimous consent that the Subcommittee on Seapower of the Armed Services Committee be authorized to meet during the session of the Senate on May 8, 2013, at 9:30 a.m.

The PRESIDING OFFICER. Without objection, it is so ordered.

#### SUBCOMMITTEE ON STRATEGIC FORCES

Mrs. BOXER. Mr. President, I ask unanimous consent that the Subcommittee on Strategic Forces of the Senate Committee on Armed Services be authorized to meet during the session of the Senate on May 8, 2013, at 2:30 p.m.

The PRESIDING OFFICER. Without objection, it is so ordered.

#### UNANIMOUS CONSENT AGREEMENT—EXECUTIVE CALENDAR

Mr. BLUMENTHAL. Mr. President, I ask unanimous consent that at a time to be determined by the majority leader, after consultation with the Republican leader, the Senate proceed to executive session to consider the following nominations: Calendar Nos. 39 and 41; that there be 30 minutes for debate equally divided in the usual form; that upon the use or yielding back of time, the Senate proceed to vote without intervening action or debate on the nominations in the order listed; that the motions to reconsider be considered made and laid upon the table, with no intervening action or debate; that no further motions be in order to the nominations; that any related statements be printed in the RECORD; that the President be immediately notified of the Senate's action and the Senate then resume legislative session.

The PRESIDING OFFICER. Without objection, it is so ordered.

#### ANIMAL DRUG AND ANIMAL GENERIC DRUG USER FEE REAUTHORIZATION ACT OF 2013

Mr. BLUMENTHAL. Mr. President, I ask unanimous consent that the Senate proceed to the immediate consideration of Calendar No. 31, S. 622.

The PRESIDING OFFICER. The clerk will report the bill by title.

The assistant bill clerk read as follows:

A bill (S. 622) to amend the Federal Food, Drug, and Cosmetic Act to reauthorize user fee programs relating to new animal drugs and generic new animal drugs.

There being no objection, the Senate proceeded to consider the bill.

Mr. BLUMENTHAL. Mr. President, I further ask unanimous consent that the bill be read a third time and passed and the motion to reconsider be made and laid upon the table, with no intervening action or debate.

The PRESIDING OFFICER. Without objection, it is so ordered.

The bill (S. 622) was ordered to be engrossed for a third reading, was read the third time, and passed, as follows:  
S. 622

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

#### SECTION 1. SHORT TITLE.

This Act may be cited as the "Animal Drug and Animal Generic Drug User Fee Reauthorization Act of 2013".

#### SEC. 2. TABLE OF CONTENTS; REFERENCES IN ACT.

(a) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title.

Sec. 2. Table of contents; references in Act.

##### TITLE I—FEES RELATING TO ANIMAL DRUGS

Sec. 101. Short title; finding.

Sec. 102. Definitions.

Sec. 103. Authority to assess and use animal drug fees.

Sec. 104. Reauthorization; reporting requirements.

Sec. 105. Savings clause.

Sec. 106. Effective date.

Sec. 107. Sunset dates.

##### TITLE II—FEES RELATING TO GENERIC ANIMAL DRUGS

Sec. 201. Short title; finding.

Sec. 202. Authority to assess and use generic new animal drug fees.

Sec. 203. Reauthorization; reporting requirements.

Sec. 204. Savings clause.

Sec. 205. Effective date.

Sec. 206. Sunset dates.

(b) REFERENCES IN ACT.—Except as otherwise specified, amendments made by this Act to a section or other provision of law are amendments to such section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

##### TITLE I—FEES RELATING TO ANIMAL DRUGS

#### SEC. 101. SHORT TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the "Animal Drug User Fee Amendments of 2013".

(b) FINDING.—Congress finds that the fees authorized by the amendments made in this

title will be dedicated toward expediting the animal drug development process and the review of new and supplemental animal drug applications and investigational animal drug submissions as set forth in the goals identified, for purposes of part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Energy and Commerce of the House of Representatives and the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate as set forth in the Congressional Record.

#### SEC. 102. DEFINITIONS.

Section 739 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j-11) is amended to read as follows:

#### "SEC. 739. DEFINITIONS.

"For purposes of this part:

"(1) The term 'animal drug application' means an application for approval of any new animal drug submitted under section 512(b)(1). Such term does not include either a new animal drug application submitted under section 512(b)(2) or a supplemental animal drug application.

"(2) The term 'supplemental animal drug application' means—

"(A) a request to the Secretary to approve a change in an animal drug application which has been approved; or

"(B) a request to the Secretary to approve a change to an application approved under section 512(c)(2) for which data with respect to safety or effectiveness are required.

"(3) The term 'animal drug product' means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the national drug code, and for which an animal drug application or a supplemental animal drug application has been approved.

"(4) The term 'animal drug establishment' means a foreign or domestic place of business which is at one general physical location consisting of one or more buildings all of which are within 5 miles of each other, at which one or more animal drug products are manufactured in final dosage form.

"(5) The term 'investigational animal drug submission' means—

"(A) the filing of a claim for an investigational exemption under section 512(j) for a new animal drug intended to be the subject of an animal drug application or a supplemental animal drug application; or

"(B) the submission of information for the purpose of enabling the Secretary to evaluate the safety or effectiveness of an animal drug application or supplemental animal drug application in the event of their filing.

"(6) The term 'animal drug sponsor' means either an applicant named in an animal drug application that has not been withdrawn by the applicant and for which approval has not been withdrawn by the Secretary, or a person who has submitted an investigational animal drug submission that has not been terminated or otherwise rendered inactive by the Secretary.

"(7) The term 'final dosage form' means, with respect to an animal drug product, a finished dosage form which is approved for administration to an animal without substantial further manufacturing. Such term includes animal drug products intended for mixing in animal feeds.